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November 18, 2014

VIA ECF
Honorable Paul A. Engelmayer
United States District Judge
Thurgood Marshall United States Courthouse
40 Foley Square
New York, New York 10007

Re: *In re Sanofi Securities Litigation*, No. 13 Civ. 8806 (PAE)

Dear Judge Engelmayer:

We write on behalf of Lead Plaintiff in the above-referenced action, and in response to Defendants' November 17, 2014 letter (the "Letter"). The Letter contains several inaccuracies that Lead Plaintiff wishes to correct.

First, while the Second Circuit allows courts, on a motion to dismiss, to take judicial notice of "the fact that press coverage, prior lawsuits, or regulatory filings contained certain information" it strictly prohibits courts from considering any facts contained in such documents for their "truth." *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008).[1] Stated another way, courts may consider that certain information is publicly disclosed (for example, if the court is analyzing a defense based on the running of the statute of limitations that turns on when a plaintiff was on inquiry notice) but it may not use the facts in such

[1] Respectfully, Defendants reliance on *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395 (S.D.N.Y. 2013) for the contrary proposition is misplaced. To reach the holding cited by Defendants, that case relies on *Gale v. Smith & Nephew, Inc.*, which held that "[t]he Court takes judicial notice of this fact, based on FDA public records available at http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040033a.pdf." 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013). That case, in turn, relied on the holding in *In re Zyprexa Prods. Liab. Litig.*, which held that "[j]udicial notice can be taken of prior complaints and legal proceedings, press releases and news articles and published analyst reports in *determining what the market knew*." 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) (emphasis added). The rule in *Zyprexa*, of course, is consistent with the Second Circuit's ruling in *Staehr v. Hartford Fin. Servs. Grp., Inc.*, cited above. Thus, it is clear – when the full lineage of the holding upon which Defendants purport to rely is reviewed – that regulatory documents may not be relied upon for the truth of their contents on a motion to dismiss.

documents to weigh whether the substantive allegations of the complaint are correct or whether a claim has been stated (exactly the purpose for which Defendants submit the FDA approval at issue here). This rule makes sense. To hold otherwise would necessarily require courts to engage in fact-based analyses on a motion to dismiss, which is impermissible.

Second, the Letter's representation that the FDA "approved Lemtrada based on data from the same rater-blinded Phase 3 clinical studies that formed the basis of Genzyme's original sBLA" is a carefully crafted red herring. Whether Lead Plaintiff adequately alleges Defendants' fraud does not implicate whether the data sets between the two applications are the same or similar; Lead Plaintiff's core complaint is that Defendants failed to disclose that the FDA repeatedly warned them of the defects in the application, that Defendants failed to correct those defects, and that the correction of those defects (or the failure to correct those defects) would bear on whether (and most notably for CVR holders, when) Lemtrada would be approved.

Indeed, as the FDA's approval itself notes, the application approved is the Company's "supplemental application, as amended."[2] This is in line with the Company's representation on April 7, 2014 that its "resubmission will provide information to specifically address issued note by the FDA in its December 27, 2013 Complete Response Letter."[3] Thus, it is perfectly reasonable that the FDA approved Lemtrada this time around: Defendants finally gave the FDA that which it had been demanding (unbeknownst to the public during the Class Period) all along.

Finally, by relying on the FDA's approval of Lemtrada, Defendants are now attempting to establish their innocence by hindsight for making false statements and actionably omitting to disclose the FDA's repeated warnings years before. This is improper, and should not be countenanced by this Court. *Florida State Bd. of Admin. v. Green Tree Fin. Corp*., 270 F.3d 645, 661-662 (8th Cir. 2001) ("The defendants contend that Coss's compensation is irrelevant because Coss wound up giving back a proportional amount of his 1996 compensation after the 1996 earnings were restated in January 1998. But Coss did not necessarily know at the time of the alleged misrepresentations and omissions that it would turn out that way. He could have acted recklessly to pile up earnings before his contract ran out, gambling that he would get away with it. **The ultimate profitability of a course of conduct is not conclusive of intent. Just as we cannot countenance pleading fraud by hindsight, neither can we infer innocence by hindsight because the alleged misdeeds did not pay off**.") (emphasis added).

Respectfully submitted,

/s/ Christopher L. Nelson
Christopher L. Nelson

cc: All counsel of record (via ECF and e-mail)

[2] FDA Approval Letter, page 1, as enclosed with the Letter. (Dkt. No. 55).

[3] *See* Joint Sanofi-Genzyme Press Release, April 7, 2014: Genzyme to Resubmit Lemtrada™ Application for FDA Review. Declaration of Joshua S. Amsel in Support of Defendants' Motion to Dismiss, Exhibit 52. (Dkt. No. 50).